

## **REMARKS**

Claims 1-15 and 17-26 are pending. Claims 3-9 and 19-26 are withdrawn from consideration. Claims 1, 2, 10-15, and 17-18 are under examination. In the present amendment, Applicants amend claims 1-2, 10-13, and 17-18 to recite “at least one archaeal polymerase and/or at least one archaeal polymerase fragment having polymerase activity.” These amendments are supported in the specification, for example, at page 10, line 6, through page 11, line 2. No new matter is added by the present amendment. Applicants respectfully request entry of the present amendment.

**I. Rejection of Claims 1, 2, 10-15, 17, and 18 Under 35 U.S.C. § 112, First Paragraph**

The Examiner rejected claims 1, 2, 10-15, 17, and 18 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.<sup>1</sup> Final Office Action at page 2.

Specifically, the Examiner stated that:

The specification as filed, is enabled for a DNA polymerase from *Pyrococcus furiosus*, but is not enabled for a DNA polymerase from any and all “samples”.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all sources to see if they contained the claimed enzyme.

*Id.* at page 3. Applicants respectfully traverse.

A claim is enabled if one skilled in the art can make and use the claimed invention without undue experimentation. Whether experimentation is undue is based, in part, on the guidance provided in the specification and the level of skill in the art.

M.P.E.P. § 2164.01 at 2100-178 – 2100-179 (8<sup>th</sup> ed. rev. 1, 2003). Applicants submit

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<sup>1</sup> The Examiner actually rejected claims 1, 2, 10-16, 17, and 18. Final Office Action at page 2. Presumably, the Examiner intended to reject claims 1, 2, 10-15, 17, and 18, because claim 16 was canceled in the Amendment and Response filed October 16, 2003.

that claims 1, 2, 10-15, 17, and 18 meet the standard of enablement for the reasons set forth in the Amendment and Response filed October 16, 2003, which is incorporated herein by reference.

Applicants further submit that the Examiner is incorrect in asserting that one skilled in the art would need “to test any and all sources to see if they contained the claimed enzyme.” To the contrary, one skilled in the art would know which sources contain archaeal polymerase and/or a fragment thereof. That is, one skilled in the art would know that archaebacteria would contain archaeal polymerase and/or a fragment thereof. One skilled in the art would also know that a non-archaeal cell, such as a mammalian cell, most likely would not contain archaeal polymerase and/or a fragment thereof, unless that cell was engineered to express recombinant archaeal polymerase and/or a fragment thereof. Armed with this knowledge, one skilled in the art would not need to engage in trial-and-error testing of “all sources,” as the Examiner appears to suggest. Thus, the Examiner fails to establish that undue experimentation would be needed for one skilled in the art to obtain an archaeal polymerase and/or an archaeal polymerase fragment using the claimed methods.

The Examiner also appears to argue that the specification is allegedly not enabled for purification of a recombinantly produced archaeal polymerase and/or a fragment thereof from a sample, based on the following statement:

Applicant has only shown in their examples one source of the claimed enzyme, namely, *Pyrococcus furiosus*. . . .

Applicant argues that the specification recites that recombinantly produced archaeal polymerases that are purified by the novel methods of the invention are known but the invention only shows that this type of enzyme was successfully used in the purification system.

Final Office Action at page 3. By this statement, the Examiner appears to require that the specification show an example of the purification of archaeal polymerase, such as recombinantly produced archaeal polymerase, from a sample other than *Pyrococcus furiosus*.

Such an example is not required to meet the standard of enablement. The M.P.E.P. states that, "the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation." M.P.E.P. § 2164.02 at 2100-181. Applicants assert that the specification enables obtaining an archaeal polymerase and/or a fragment thereof from a sample other than *Pyrococcus furiosus*.

The specification provides detailed guidance on obtaining archaeal polymerase from *Pyrococcus furiosus*. See specification, Examples 1-4, at pages 16-22. Such guidance, in view of routine techniques known in the art (see Ausubel et al., submitted with Applicants' previous response), would enable one skilled in the art to obtain a recombinantly produced archaeal polymerase and/or a recombinantly produced archaeal polymerase fragment from a sample other than *Pyrococcus furiosus*. The Examiner provides no evidence that anything more than routine techniques are needed.

Thus, the Examiner has failed to establish that undue experimentation would be required to practice the claimed methods in claims 1, 2, 10-15, 17, and 18. Withdrawal of the rejection of those claims under 35 U.S.C. § 112, first paragraph, is respectfully requested.

**II. Rejection of Claims 1, 2, 10-15, 17, and 18 Under 35 U.S.C. § 103(a)**

The Examiner rejected claims 1, 2, 10-15, 17, and 18 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bezuglyi, Bernard, or Grandgenett. Final Office Action at page 4. This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the cited documents must have suggested all the claim elements. M.P.E.P. § 2143 at 2100-124 – 2100-125. None of the cited documents, either singly or in combination, would have suggested obtaining an archaeal polymerase and/or archaeal polymerase fragment. Therefore, the cited documents would have failed to render the claims obvious.

Furthermore, the Examiner appears to argue that it would have been obvious to modify the cited documents to include archaeal cells and archaeal polymerases.

Specifically, the Examiner alleged that:

The references each teach a DNA polymerase being purified using PolyU Sepharose chromatography.

It would have been obvious to use the specific types of [archaeal] polymerases and cells since such cells and enzymes are well known in the art. To use such enzymes and cells are simply the choice of the artisan in an effort to optimize the desired results.

Final Office Action at page 4.

To modify the cited documents, the Examiner must provide some motivation or suggestion to do so. See M.P.E.P. § 2143.01 at 2100-125. The Examiner has failed to meet this burden. In fact, it is the Applicants' own disclosure that provides such a suggestion or motivation. See, e.g., specification at page 4, lines 6-14, disclosing a motivation to obtain highly purified archaeal polymerase, so that PCR can be optimized through the controlled addition of accessory factors. The Examiner may not rely on the

Applicant's own disclosure to supply the necessary motivation. M.P.E.P. § 2143 at 2100-125.

The Examiner further stated that, "[t]o use such archaebacterial DNA polymerases is known in the art as is shown by applicant's own admission of the art as shown by Lasken et al. on page 2 of the applicant's specification." Final Office Action at page 4. Lasken observed that PCR reactions using archaeal polymerases were inhibited in the presence of dUrd-containing oligonucleotides, whereas PCR reactions using non-archaeal polymerases were not inhibited in the presence of dUrd-containing oligonucleotides. Specification, paragraph bridging pages 2-3. The fact that certain archaeal polymerases may have been known in the art and used in PCR reactions would not have rendered the claims obvious, because such polymerases and uses are not what is claimed. The claims encompass a method of obtaining at least one archaeal polymerase and/or at least one archaeal polymerase fragment. Thus, Lasken would have failed to cure the deficiencies of Bezuglyi, Bernard, or Grandgenett.

Furthermore, Bezuglyi, Bernard, or Grandgenett, in view of Lasken's observations, would not have suggested the desirability of purifying archaeal polymerases and/or fragments thereof using the claimed methods. See M.P.E.P. § 2143.01 at 2100-125 ("The prior art must suggest the desirability of the claimed invention."). As discussed above, it is the Applicants' own specification that suggests obtaining substantially pure archaeal polymerase, so that PCR can be optimized through the controlled addition of accessory factors. In contrast, the mere allegation that the method of Bezuglyi, Bernard, or Grandgenett *could have been* used to purify known archaeal polymerases does not render the claims obvious. See M.P.E.P.

§ 2143.01 at 2100-126 (citing *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990) ("The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.") (emphasis in original).

Accordingly, the Examiner has failed to establish obviousness of claims 1, 2, 10-15, 17, and 18. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

### **CONCLUSION**

Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the application. In the event that the Examiner does not find the application allowable, Applicants request that the Examiner contact the undersigned at (650) 849-6778 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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